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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/115,589	07/15/1998	JENNIFER E. VAN EYK	12917	1553

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EXAMINER	
BORGEEST, CHRISTINA M	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/115,589	VAN EYK ET AL.	
	Examiner	Art Unit	
	Christina Borgeest	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *56-102* is/are pending in the application.

4a) Of the above claim(s) *99-102* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *56-98* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

The text of those sections of Title 35, U.S.C. not included in this action can be founding a prior Office action.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 13 July 2005 has been entered. Claims 1-55, 60-61, 70, 85-86 have been cancelled, and claim 88 was amended to correct a typographical error. Claims 99-102 are new. Claims 56-59, 52-66, 68-69, 71-84, 87-98 are pending and under examination. Claims 99-102 are withdrawn from consideration and not under examination, as they are drawn to a non-elected species.

Election/Restrictions

Applicant's election with traverse of 18 October 2005 in the reply filed on 18 November 2005 is acknowledged. The traversal is on the ground(s) that the instant application has been subjected to two restriction requirements and that full faith and

credit be given to the searches by Examiner Gucker. This argument is found fully persuasive and the restriction requirement mailed 18 October 2005 is withdrawn.

Newly submitted claims 99-102 contains subject matter that is independent or distinct from the invention originally claimed for the following reasons: Applicants' election filed 3/10/00 limits the instant claims to the methods employing troponin I and residues 1-193 of troponin I (SEQ ID NO: 21) and excludes as non-elected troponin T and troponin C.

Furthermore, Applicants' election filed 3/10/00 limits the instant claims to the methods employing troponin I and residues 1-193 of troponin I (SEQ ID NO: 21) and excludes as non-elected troponin T, troponin C, α-actinin, and SEQ ID NOs: 22, 23, 24, 25, 26, 27, 30, 31, 32, 33. Therefore, the instant claims are only being examined to the extent that they read on methods employing troponin I and residues 1-193 of troponin I (SEQ ID NO: 21). Applicants' election filed 3/10/00 limits the instant claims to methods employing a myosin light chain 1 pepetide fragment comprising residues 20-199, which almost corresponds to SEQ ID NO: 28, and excludes other myosin light chain 1 peptide fragments such as SEQ ID NO: 29.

In their correspondence filed 28 March 2005, Applicants' point out that the original species elections were made with traverse, and that more than one species of an invention may be claimed in different claims in one application provided that the application includes an allowable claim generic to all the claimed species and all claims to species in excess of one are written in dependent form. Applicants' arguments have

been fully considered but they are not persuasive. There is no one allowable claim generic to all the claimed species in the instant claims.

Objections/Rejections Withdrawn

Claim Rejections - 35 USC § 112

The rejection of claims 56-59, 71-84 and 96-98 under 35 U.S.C., second paragraph is withdrawn in light of Applicants' amendment of claims 56, 80 and 97 to include method steps.

The rejection of claim 69 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of Applicants' amendment of the claim.

Objections/Rejections Maintained/New Rejections

Objection to Specification - 35 USC 132

The amendment filed 6 August 2004 was objected to under 35 USC 132 as introducing new matter added at paragraph beginning at p. 10, line 21, page 12, line 14 and p. 14, line 3, to replace "192" with "199". Applicants argue that they have amended the sequence and provided a CRF copy of the sequence listing, and that the amendment is now including of both the MLC1 rat sequence of 199 amino acids as SEQ ID NO: 28 and the corresponding shorter human MLC1 sequence. Applicants'

arguments have been fully considered but they are not persuasive. Applicants have provided no compelling evidence in this case that they were correcting an obvious error, rather the amendment appears to be an attempt to obtain broader coverage. For this reason the objection to the specification under 35 USC 132 is maintained.

With regard to the amended paragraphs to p. 9, line 21, p. 29, line 4 and p. 32, line 19 relating to the epitope TnI amino acid residues not supported by original disclosure, Applicants argue that the amendment was to correct an obvious error, and that the specification taught on p. 29, line 21 that the anti-TnI antibody was obtained from Spectral Diagnostics, and Applicants provided a copy of the web page for anti-cardiac TnI Mab 8I-7 from Spectral Diagnostics disclosing the epitope for this antibody to be amino acid residues 137 to 148. Applicants' arguments have been fully considered and are persuasive. The examiner finds no issue with the correction of errors at p. 9, line 21, p. 29, line 4 and p. 32, line 19 relating to the epitope TnI amino acid residues.

Claim Rejections - 35 USC § 102

Claims 56-59, 62-65, 68-69, 71-84, 87-90 and 92-98 are rejected under 35 U.S.C. 102(b) as being anticipated by Löfberg et al. for reasons of record (see Office Actions mailed 7 April 2004 and 13 January 2005). Applicants suggest that the amendment of the claims to state the intact protein is an intact myofilament protein overcomes the prior art rejection. Applicants' arguments have been fully considered but they are not persuasive. The claims recited peptide elements written in the alternative,

so claim 56 is drawn in part to a method comprising detecting the presence or absence or measuring the amount of a peptide fragment of a myofilament protein in a biological sample obtained from a subject being assessed for cardiac muscle damage by incubating the biological sample with an antibody that specifically binds to the peptide fragment of a myofilament protein under conditions which allow the antibody or functional fragment of the antiobody to form a complex with the peptide fragment of a myofilament protein and detecting or measuring the formed complex wherein said peptide fragment consists of all or a portion of a cardiac troponin I peptide fragment and wherein the presence or amount of the peptide fragment of the myofilament protein in the biological sample is associated with cardiac muscle damage. Thus, Löfberg et al. still reads on all the limitations of the claims. Löfberg et al teach the use of various antibodies and detectable labels and markers (iodine-125, antibodies conjugated to solid-phase magnetic particles, and immunoenzymometric assays, pp. 1211-1212) to detect two different fragments of myosin heavy-chain, troponin I, and troponin T for the purpose of assaying acute muscle damage, irreversible cardiac and skeletal muscle damage, and reversible cardiac and skeletal muscle damage from biological samples such as serum (pages 1211-1212).

Claims 56-59, 62-65, 68-69 and 71-84, 87-98 are rejected under 35 U.S.C. 102(b) as being anticipated by Wicks et al. (WO 94/27156) for reasons of record (see Office actions mailed 7 April 2004 and 13 January 2005). Applicants suggest that the amendment of the claims to state the intact protein is an intact myofilament protein

overcomes the prior art rejection. Applicants' arguments have been fully considered but they are not persuasive for the reason stated above. Wicks discloses the use of antibodies and detectable labels and markers (enzymes, alkaline phosphatase, page 12) to detect troponin I and troponin C in a complex in sandwich assays having immobilized solid phases for the purpose of assaying irreversible cardiac damage from biological samples such as blood (pp. 2-5).

Claims 56, 62-66, 68-69 and 71-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Takahashi et al (WO 96/10078) for reasons of record (see Office Actions mailed 7 April 2004 and 13 January 2005). Applicants suggest that the amendment of the claims to state the intact protein is an intact myofilament protein overcomes the prior art rejection. Applicants' arguments have been fully considered but they are not persuasive for the reason stated above. Takahashi teaches the use of antibodies and detectable labels and markers (enzymes, peroxidase and alkaline phosphatase, pages 6-7 and 9) to detect myosin light chain 1 (MLC-I) in a complex in sandwich assays having immobilized solid phases (pages 10 and 12) for the purpose of assaying cardiac damage from biological samples such as blood (pages 2-5).

Finally, claims 56-59, 62-65, 68-69, 71-84, 87-90 and 92-98 are rejected under 35 U.S.C. 102(b) as being anticipated by Westfall et al. for reasons of record (see Office Actions mailed 7 April 2004 and 13 January 2005). Applicants do not specifically argue against Westfall et al., but rather state that their amendment to the claims to recite "the

intact protein is an intact myofilament protein" clearly distinguishes the present invention from teachings of Lofberg, Westfall, Wicks and Takahashi wherein the intact protein is not an intact myofilament protein, but rather, as stated by the Examiner, an antibody. This argument has been fully considered, but not found persuasive.

The claims recited peptide elements written in the alternative, so claim 56 is drawn in part to a method comprising detecting the presence or absence or measuring the amount of a peptide fragment of a myofilament protein in a biological sample obtained from a subject being assessed for cardiac muscle damage by incubating the biological sample with an antibody that specifically binds to the peptide fragment of a myofilament protein under conditions which allow the antibody or functional fragment of the antiobody to form a complex with the peptide fragment of a myofilament protein and detecting or measuring the formed complex wherein said peptide fragment consists of all or a portion of a cardiac troponin I peptide fragment and wherein the presence or amount of the peptide fragment of the myofilament protein in the biological sample is associated with cardiac muscle damage. Thus, Westfall et al. still reads on all the limitations of the claims. Westfall teaches the use of various antibodies and detectable markers (alkaline phosphatase, page 303) to detect fragments from both troponin I and troponin T (abstract) for the purpose of assaying cardiac muscle damage from ischemia from biological samples such as a component of cardiac muscle tissue (page 303). The amount of damage is correlated with time of ischemia (30 minutes as compared to 60 minutes) and ratios were established between the gradual reduction of whole troponins

and the appearance of troponin fragments (pages 307-308, Figures 10 and 11 and Table 1).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is 571-272-4482. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christina Borgeest, Ph.D.

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER